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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,228	03/16/2004	Michael N. Helmus	03-089	2014

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MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
09/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,228	HELMUS ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-10 and 24-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-10 and 24-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 06/146/2008.

Claims 1-3 and 11-23 have been canceled.

Claims 24-31 have been added.

Claims 4-10 and 24-31 are pending and included in the prosecution.

Specification

1. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

2. Applicants have not indicated review or showed any correction made to the specification; therefore, the objection made to the specification is maintained.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4-10 and 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 6,545,097 ('097) and US 4,475,972 ('972).

US '097 teaches intravascular medical device for implantation in the body of patient comprises biocompatible block copolymer (abstract). The block copolymer preferable comprises isobutylene block and styrene block and triblock copolymer of polystyrene-polyisobutylene-polystyrene (col.1, line 65-col.2, line 3; col.5, lines 15-18; col.21, lines 1-14). The block copolymer has the advantage of having high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels (col.5, lines 15-29). The devices are produced by forming solution of the block

copolymers that undergoes spinning and can be in the form of fibers, the reference disclosed drying of block copolymer by solvent evaporation (col.14, lines 30-37, 47-63). Solution is made by solvent including tetrahydrofuran or hexane (col.14, lines 54-55). Medical devices produced by the disclosed block copolymers are porous and tubular and including stent graft (col.13, line 59; col.14, line 63; col.15, lines 6-8).

Although US '097 suggested spinning of polymer solution, and fiber formation, and evaporation of solvent, however, the reference does not explicitly teach fibers formed by dry spinning as claimed by claim 1. The reference does not teach fibers forming woven and non-woven regions as claimed by claims 5 and 6, or the fibers are thermally bonded as claimed by claim 7 and 8.

US '972 teaches tubular porous biocompatible polymer suitable for vascular devices (abstract). The device is produced by spinning solution of the polymer and the solvent is evaporated by heat during winding of the filaments, i.e. dry spinning (col.4, lines 3-15). Evaporation of the solvent provides non-woven structure (col.3, line 12; col.4, lines 8-10; col.5, lines 43-46). Woven structures also disclosed (col.5, line 33). The fibers are bonded together upon evaporating the solvent (col.1, lines 35-38; col.4, lines 5-7). The method of dry spinning provides improved procedure for formation of porous tubular material suitable for medical vascular devices having high suturing strength and high toughness to resist cyclic fatigue (col.1, lines 33-50).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device comprises block copolymer of polyisobutylene and styrene that can be in the form of fibers as disclosed by Us '097,

and produce the fibers by dry spinning that provide fiber to fiber bonding as disclosed by US '972 because US '972 teaches that such a method provides improved procedure for formation of porous tubular material suitable for medical vascular devices having high suturing strength and high toughness to resist cyclic fatigue, with reasonable expectation of having tubular porous medical device comprises block copolymer of polyisobutylene and styrene fibers produced by dry spinning that have high suturing strength and high toughness to resist cyclic fatigue.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tubular porous vascular medical device comprises biocompatible fibers produced by dry spinning as disclosed by US '972, and replace the biocompatible polymer with the block copolymer comprising isobutylene and styrene disclosed by US '097 because US '097 disclosed such block copolymer has the advantage of high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels, with reasonable expectation of having tubular porous vascular medical device comprises biocompatible fibers of block copolymers of styrene and isobutylene produced by dry spinning that has high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels.

Response to Arguments

Applicant's arguments filed 06/13/2008 have been fully considered but they are not persuasive. Applicants argue that the combination of references as proposed in the Office Action does not render the present invention obvious. In this regard, a proper rejection under 35 U.S.C. 103 requires must include an explanation as to why one of ordinary skill in the art at the time the invention was made would have been motivated to make a proposed modification to the prior art to arrive at the claimed subject matter, and there must be a reasonable expectation of success. Applicants further argue that one or ordinary skill in the art, at the time the invention was made, would not have had a reasonable expectation of success in forming dry spun fibers from styrene-isobutylene copolymers including SIBS copolymers because these copolymers are not known as fiber-forming polymers.

In response to these argument, it is argued that the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device comprises block copolymer of polyisobutylene and styrene that can be in the form of fibers as disclosed by US '097, and produce the fibers by dry spinning that provide fiber to fiber bonding as disclosed by

US '972 because US '972 teaches that such a method provides improved procedure for formation of porous tubular material suitable for medical vascular devices having high suturing strength and high toughness to resist cyclic fatigue, with reasonable expectation of having tubular porous medical device comprises block copolymer of polyisobutylene and styrene fibers produced by dry spinning that have high suturing strength and high toughness to resist cyclic fatigue.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide tubular porous vascular medical device comprises biocompatible fibers produced by dry spinning as disclosed by US '972, and replace the biocompatible polymer with the block copolymer comprising isobutylene and styrene disclosed by US '097 because US '097 disclosed such block copolymer has the advantage of high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels, with reasonable expectation of having tubular porous vascular medical device comprises biocompatible fibers of block copolymers of styrene and isobutylene produced by dry spinning that has high tensile strength, resists cracking and degradation under in vivo condition, and exhibits excellent vascular compatibility and ability to minimize thrombotic occlusion of small vessels.

Therefore, there is motivation to combine the references and reasonable expectation of success because US '097 teaches fiber formation and further teaches that spinning can be one of the methods of forming the fibers (co.14, lines 33-38, 55-58). Further, US '097 teaches the method of making the fibers from styrene butylene

block copolymer including the steps of using solvent to form solution of the polymer, and suggested extrusion or spinning the polymer solution to form fibers or sheet, followed by evaporation of the solvent. Applicants used the same method of making the claimed fibers, example one of the present specification. Therefore, the method of making the fibers disclosed by the reference suggested the present method, and expected to provide the same product. Additionally, at the time of the invention the art recognized formation of fibers from styrene butylene block copolymers as disclosed by US '097, and also the art recognized the dry spinning. In any event dry spinning is directed to method of making, and the present claims are product by process claims, and product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. *In re Thorpe,* 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), wherein the product-by-process claim was rejected because the end product, in both the prior art and the claimed product were the same. The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final

product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). Since the claimed product appears to be substantially identical to that of the prior art, the burden is shifted to applicant to show an unobvious difference between the claimed product and the prior art product and to come forward with evidence establishing an unobvious difference. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974); *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983); *Ex parte Gray*, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989). It has been held that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtains prior art products and makes physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

It has been held that: "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.*, 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of

elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions."

A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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